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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

HELSINN HEALTHCARE S.A. and  
ROCHE PALO ALTO LLC,

Plaintiffs,

v.

DR. REDDY'S LABORATORIES, LTD.,  
DR. REDDY'S LABORATORIES, INC.,  
SANDOZ, INC., TEVA PHARMACEUTICALS  
USA, INC., and TEVA PHARMACEUTICAL  
INDUSTRIES, LTD.,

Defendants.

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)  
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)  
) Civil Action No. 11-3962 (MLC)(DEA)  
) Civil Action No. 11-5579 (MLC)(DEA)  
) (consolidated)  
)  
) Hon. Mary L. Cooper, U.S.D.J.  
) Hon. Douglas E. Arpert, U.S.M.J.  
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**MEMORANDUM IN SUPPORT OF TEVA'S  
MOTION TO AMEND ITS INVALIDITY CONTENTIONS**

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## **INTRODUCTION**

Pursuant to Local Patent Rules 3.6 and 3.7, Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively, “Teva”), respectfully requests the Court’s leave to amend its Invalidity Contentions to add a 102(b) defense that the asserted patents (U.S. Patent Nos. 7,947,724; 7,947,725; and 7,960,424) are invalid under the on-sale bar. The on-sale bar of 35 U.S.C. § 102(b) provides that “[a] person shall be entitled to a patent unless the invention was ... on sale in this country, more than one year prior to the date of the application for patent in the United States.” Teva seeks to amend its contentions to add this defense based on facts discovered in reviewing Plaintiffs’ document production and a recent 30(b)(6) deposition of Plaintiffs’ witness on this topic, which occurred just last week.

Teva notes that Plaintiffs have been on notice of this on-sale bar defense and actively litigating it because defendant Sandoz, Inc. (“Sandoz”) sought and was granted leave in September 2012 to amend its contention to add this same defense. Because this issue has been the subject of fact discovery and no new discovery will be required, Plaintiffs cannot show that they will be unfairly prejudiced. By granting this motion, the Court will ensure that all relevant and material defenses to Plaintiffs’ infringement claims are considered. For all of these reasons, Teva’s motion to amend its Invalidity Contentions should be granted.<sup>1</sup>

### **I. BACKGROUND**

The sequence of events in this case demonstrates that Teva has been diligent in its investigation of the on-sale bar defense. Teva served Plaintiffs with its Invalidity Contentions on

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<sup>1</sup> To the extent that the Court grants leave to any of the other defendants to supplement their invalidity contentions, Teva requests that it be permitted to incorporate by reference any such invalidity contentions.

December 1, 2011. (*See* Teva's Invalidity Contentions, attached as Ex. 1.)<sup>2</sup> Consistent with the parties' agreement on the deadline for substantial completion of document production, Plaintiffs served Teva on November 14, 2012 with a document production consisting of approximately 222,422 pages, which was more than double the production that Plaintiffs had previously produced to date. (11/14/12 letter from Cylena L. Abrahams, attached as Ex. 2.) This production included significant documentation related to the sale and/or offer for sale of the claimed invention prior to the critical date, January 30, 2002. Among other things, the documents revealed the negotiation of a development and manufacturing agreement between Helsinn and Oread, Oread's manufacture for Helsinn of batches embodying the claimed invention, and Helsinn's selection of Oread to make clinical and commercial palonosetron drug products. (*See, e.g.*, HELSN0388553-569, HELSN0388587-597, HELSN0388604-609, HELSN0389134-161, HELSN0392047-48, HELSN0392393-94, attached as Exs. 3a, 3b, 3c).

The parties also only recently began taking fact depositions in this case. On November 20, 2012, Defendants served Plaintiffs with notice for deposition under Fed. R. Civ. P. 30(b)(6). The deposition topics included several directly related to on-sale bar issues, including topics 1-4 relating to the development and completion of the claimed invention and topics 15 and 23-27 relating to the commercialization and sale of the claimed invention. (11/20/12 Defendants' 30(b)(6) Notice, attached as Ex. 5.) By email on January 4, 2013, Plaintiffs designated Dr. Giorgio Calderari, the first named inventor of the patents-in-suit, as a 30(b)(6) witness and agreed to his deposition on February 6, 2013. (1/4/13 email from Dana Weir, attached as Ex. 6.) By another email on January 15, 2013, Plaintiffs indicated that Dr. Calderari to be their 30(b)(6) witness on topics 1-4, 6, 10, 24-25, and 27. (1/15/13 email from Dana Weir, attached as Ex. 7.)

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<sup>2</sup> The exhibits referenced herein are attached to the Declaration of Mayra V. Tarantino submitted herewith.

On January 17, 2013, the Court held an in-person status conference where the parties agreed that Dr. Calderari's deposition would be held for seven hours on the record on February 8, 2013 and for an additional three hours on the record on February 9, 2013, because of the breadth of Dr. Calderari's testimony. The Court was also informed that Defendants would be seeking leave to amend their respective invalidity contentions. Specifically, Teva stated that it expected to amend its invalidity contentions, and requested from the Court the same consideration that it would give the other defendants on this issue.

On February 8 and 9, 2013, Dr. Calderari was deposed. Dr. Calderari's testimony related to topics including "the research and development relating to the palonosetron formulations claimed in the asserted claims," "matters relating to the decision by Helsinn to contract with Oread concerning palonosetron solutions," and "matters relating to the development work performed by Oread at Helsinn's request with respect to palonosetron solutions." (Calderari Dep. Ex. 6, attached as Ex. 8.) Dr. Calderari's testimony corroborated and/or confirmed many of the issues related to the on-sale bar defense, for example, that the claimed invention was completed prior to the critical date, and that Helsinn and Oread contracted to manufacture palonosetron drug products that embodied the claimed invention prior to the critical date. (Excerpts from Calderari Dep. Tr. 229:1-230:4, 336:4-346:20, 369:2-382:11, 386:9-392:10, attached as Ex. 9.) Dr. Calderari further confirmed that prior to the critical date, Helsinn entered into a relationship with another third party manufacturer, SP Pharmaceuticals ("SP"), to manufacture commercial palonosetron drug products, and that Helsinn contracted with a third party distributor, MGI Pharma, Inc. ("MGI"), to distribute the commercial palonosetron drug products. (*Id.* at 280:6-301:5, 346:21-368:14.)

On February 12, 2013, the parties agreed on a schedule for briefing concerning Defendants' proposed amended invalidity contentions. (2/12/13 letter from Eric Abraham, attached as Ex. 10.) By email on February 13, 2013, Teva sent to Plaintiffs its proposed Amended Invalidity Contentions regarding the addition of the on-sale bar defense, and asked whether Plaintiffs would consent to this amendment. (2/13/13 email from Jovial Wong, attached as Ex. 11.) On February 14, 2013, Plaintiffs said they oppose the amendment. (2/14/13 email from Dana Weir, attached as Ex. 12.)

Notably, Plaintiffs will not be prejudiced by Teva's proposed amendment because they have been on notice at least since September 2012 that issues related to the invalidity of the patents-in-suit under the § 102(b) on-sale bar would be part of this case. (*See* Sandoz' First Amended Invalidity Contentions.) Accordingly, no additional discovery aside from that already contemplated will be required.

## II. LEGAL STANDARD

Section 3.7 of the Local Patent Rules provides that amendment of a party's Invalidity Contentions may be made by order of the Court "upon a timely application and showing of good cause." L. Pat. R. 3.7.<sup>3</sup> "The Local Patent Rules 'exist to further the goal of full, timely discovery and provide all parties with adequate notice and information with which to litigate their cases.'" *Int'l Development, LLC v. Richmond*, No. 09-2495, 2010 WL 3946714, at \*3 (D.N.J. Oct. 4, 2010) (Arpert, J.) (quoting *Computer Accelerations Corp. v. Microsoft Corp.*, 503 F. Supp. 2d 819, 822 (E.D. Tex. 2007)). As courts in this jurisdiction have noted, "Rule 3.7 is not a straightjacket into which litigants are locked from the moment their contentions are

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<sup>3</sup> As this Court has recognized, "both the District of New Jersey and the Eastern District of Texas have adopted verbatim their Local Patent Rules from the Northern District of California." Thus, it is "appropriate to look to cases from those districts for guidance." *See, e.g., TFH Publications, Inc. v. Doskocil Mfg. Co., Inc.*, 705 F.Supp.2d 361, 366 at fn. 3 (2010).



served.” *TFH Pubs., Inc. v. Doskocil Mfg. Co., Inc.*, 705 F. Supp. 3d 361, 366 (D.N.J. 2010) (internal quotations omitted). “[W]hile the Local Patent Rules strive to have a party establish its contentions early on, it is important to recognize that preliminary infringement contentions are still preliminary.” *Id.* (internal quotations omitted).

When determining whether good cause to amend invalidity contentions exists, courts consider several factors: (1) the reason for the delay and whether the party has been diligent; (2) the importance of what the court is excluding and the availability of lesser sanctions; (3) the danger of unfair prejudice; and (4) the availability of a continuance and the potential impact of a delay on judicial proceedings. *Int’l Development*, 2010 WL 3946714 at \*3.

### **III. ARGUMENT**

#### **A. Teva Has Shown Good Cause For Permitting the Proposed Amendment.**

Each of the factors considered by courts in determining whether good cause to amend invalidity contentions exists weighs in favor of allowing Teva to amend its Invalidity Contentions.

##### **1. *Teva diligently investigated the possibility of invalidity under §102(b).***

During the course of fact discovery – which still is ongoing – Teva has diligently taken discovery on the on-sale bar defense, which is highly factual in nature, before moving to amend its Invalidity Contentions. For example, Teva conducted a thorough review of Plaintiffs’ entire document production, the majority of which was only produced on November 14, 2012, and discovered numerous documents indicating that Helsinn had sold or offered for sale the claimed invention prior to the critical date of the patents-in-suit. These documents shed light on the history of transactions between Helsinn and Oread with respect to the claimed invention, as well as between Helsinn and other third parties like SP and MGI, respectively. Teva also noticed the deposition of Plaintiffs on November 20, 2012 regarding 30(b)(6) topics that directly related to

the on-sale bar defense. Teva then negotiated with Plaintiffs regarding the deposition of Dr. Calderari, who was both designated on 30(b)(6) topics relevant to this precise issue and expected to have the most knowledge of this issue in his personal capacity. Finally, Teva was able to confirm Dr. Calderari's deposition with assistance from the Court at the January 17, 2013 status conference. At the same time, Teva also made Plaintiffs and the Court aware that it was likely to amend its invalidity contentions, as did other defendants Sandoz and DRL. At Dr. Calderari's deposition on February 8 and 9, 2013, Teva was able to confirm that the claimed invention was completed and that Helsinn contracted with Oread, SP, and MGI with respect to the claimed invention prior to the critical date. On February 13, 2013, four days after the conclusion of Dr. Calderari's deposition, Teva requested consent from Plaintiffs to amend its Invalidity Contentions. When Plaintiffs declined to consent, Teva promptly filed this motion.

As detailed above, Teva has acted diligently at every step in moving to amend its Invalidity Contentions. Similarly in *Positive Techs., Inc. v. Sony Electronics, Inc.*, No. C-11-2226, 2013 WL 322556, at \*2-3 (N.D. Cal. Jan. 28, 2013), defendants moved to amend their invalidity contentions after uncovering a new prior art reference. The court held that defendants' "multi-tier review" demonstrated that they had acted diligently with respect to amending their invalidity contentions. *Id.* The court disagreed with plaintiff's argument that the amendment should have been included in defendants' initial invalidity contentions, noting that, under plaintiff's view, "amendment of invalidity contentions would either never be necessary or would be impossible because the party proposing amendments would either always be diligent the first time or would be found to lack diligence for not having thoroughly investigated the 'obviously' relevant references in the first place." *Id.* Like the defendants in *Positive Techs.*, Teva has

diligently pursued its review of the on-sale bar defense, thus supporting a finding of good cause to amend.

**2. *Teva's amendment is critically important to this case.***

If a patent application is filed more than one year after (1) the invention is the subject of a commercial sale or offer for sale and (2) the invention is ready for patenting, the patent is invalid. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67 (1998). Thus, because the invalidity under the § 102(b) on-sale will be dispositive with respect to all of the asserted claims in the case, Teva's amendment is critically important. The evidence obtained to date shows that the claimed invention was in fact sold and/or offered for sale more than one year before the filing of the inventors' patent application. *See, e.g., Delaware Valley Floral Group, Inc. v. Shaw Rose Nets, LLC*, 597 F.3d 1374 (Fed. Cir. 2010) (affirming summary judgment order declaring patent invalid under the on-sale bar); *In re Cygnus Telecommunications Tech., LLC, Patent Litig.*, 536 F.3d 1343 (Fed. Cir. 2008) (same). Moreover, public policy weighs heavily in favor of allowing all invalidity defenses to be tried against patents that are the subject of litigation. *See Nestier Corp. v. Menasha Corp-Lewisystems Div.*, 739 F.2d 1576, 1581 (Fed. Cir. 1984) ("There is a stronger public policy interest in the elimination of invalid patents than in the affirmation of a patent as valid, at least in part because patents maintain presumption of validity.").

Accordingly, the importance of this amendment weighs in favor of granting Teva's motion to amend. *See Computer Acceleration Corp. v. Microsoft Corp.*, 481 F. Supp. 2d 620, 625 (E.D. Tex. 2007) (granting motion to amend where amendment was "highly relevant and significant to [defendant's] ability to successfully defend against [plaintiff's infringement claims]"); *Avago Techs. Gen. IP Pte Ltd. v. Elan Microelectronics Corp.*, No. C04-05385, 2007 WL 1449758, at \*2 (N.D. Cal. May 15, 2007) (granting motion to leave and noting that "the court wishes to have this invalidity issue decided on the merits, in the interest of promoting

substance over form”); *Yodlee, Inc. v. CashEdge, Inc.*, No. C 05-01550, 2007 WL 145259, at \*2 (N.D. Cal. May 17, 2007) (finding good cause to amend, in part, because the subject of the amendment “may be highly material to the merits of the case”); *Streak Prods., Inc. v. Antec, Inc.*, No. C09-04255, 2010 WL 3515752, at \*3 (N.D. Cal. Sept. 8, 2010) (“Courts prefer to decide cases on the merits, rather than on procedural grounds.”).

### **3. *There is no prejudice to Plaintiffs.***

Significantly, there is absolutely no danger of prejudice to Plaintiffs in allowing Teva to amend its Invalidity Contentions to include invalidity under § 102(b) for the simple reason that Sandoz has already amended its contentions to include this defense. Plaintiffs have thus been well aware of this issue since being served with Sandoz’s Amended Contentions in September 2012. Teva’s amendment will not result in any additional work for Plaintiffs or require Plaintiffs to expend any additional resources because invalidity under § 102(b) has already been, and will continue to be, at issue in the case.<sup>4</sup> Indeed, most if not all of the evidence required to establish the on-sale bar defense will be from Plaintiffs’ own documents, which they cannot deny knowledge or control of. As several courts have noted, “[t]he patent rules’ conservative approach to amendment is designed to prevent parties from plotting a new course in litigation each time an unfavorable wind blows their way.” *Advanced Micro Devices, Inc. v. Samsung Electronics Co.*, No. C 08-00986, 2009 WL 890515, at \*2 (N.D. Cal. Apr. 1, 2009). By contrast,

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<sup>4</sup> To the extent that Plaintiffs argue that they will be prejudiced by references in Teva’s amendment to contracts between Helsinn and SP or MGI, this argument is a red herring. The same theory of invalidity under § 102(b) applies with equal force to *any* sale or offer for sale of the claimed invention made more than one year before the filing of the applications for the patents-in-suit. The fact that there may have been multiple sales or offers for sale with more than one third party does not alter this analysis. For Plaintiffs, this is simply a matter of applying a single legal theory to related sets of facts occurring within the same time frame.

Teva merely seeks to supplement its Invalidity Contentions with a defense that is already present in the case.

Courts routinely grant motions to amend invalidity contentions when there is no prejudice to the other party. *See, e.g., Zoltar Satellite Alarm Sys., Inc. v. Motorola, Inc.*, No. C06-00044, 2008 WL 913326, at \*2 (N.D. Cal. Apr. 2, 2008) (granting motion to amend where plaintiff did not identify or articulate how it would be prejudiced if the amendment was allowed); *Avago Techs.*, 2007 WL 1449758 at \*2 (granting motion to amend invalidity contentions to include defendant's theory of invalidity and finding no prejudice to plaintiff where it knew about new theory "almost three months before its opposition to the relevant summary judgment motion is due," "all of the documents that this theory is based on have been [plaintiff's] possession for at least as long as they have been in [defendant's]," and there was no reason to suspect defendant was acting in bad faith); *Halo Electronics, Inc. v. Bel Fuse Inc.*, No. C07-06222, 2010 WL 3489593, at \*2 (N.D. Cal. Sept. 3, 2010) (granting motion to amend where plaintiff could "not convincingly demonstrate[ ] that [it] would suffer serious prejudice"); *Mondis Tech., Ltd. v. LG Electronics, Inc.*, Nos. 2:07-CV-565, 2:08-CV-478, 2011 WL 2149925, at \*4 (E.D. Tex. May 5, 2011) (no significant prejudice where nothing new was added to invalidity contentions); *Yodlee*, 2007 WL 1454259 at \*3 (plaintiff was not substantially prejudiced by amendment where it had "not filed any substantive motion that will be impacted or rendered moot by [defendant's] amendment" and the case was still in discovery stage). The lack of prejudice to Plaintiffs weighs in favor of granting Teva's motion.

**4. *There will be no delay in the case.***

This is Teva's first motion for leave to amend its Invalidity Contentions. The case is still in the midst of fact discovery, and expert discovery has not yet begun. Indeed, the first fact deposition was only taken last week, and the deadline for dispositive motions is still six months

away. Moreover, no trial date has yet been set. Consequently, Teva's proposed amendment will not require any alteration of the existing case schedule and will not cause any delay in these proceedings.

**CONCLUSION**

For the foregoing reasons, Teva respectfully requests that the Court grant its motion to amend its Invalidity Contentions.

Dated: February 15, 2013

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I, Mayra V. Tarantino, hereby certify that on February 15, 2013, I caused a copy of the (a) Teva's Notice of Motion for Leave to Amend Invalidity Contentions, (b) Memorandum in Support of Teva's Motion to Amend its Invalidity Contentions, (c) Declaration of Mayra V. Tarantino, and (d) Form of Order to be served on counsel for Plaintiffs through the Court's ECF system and by email.

By: s/*Mayra V. Tarantino*  
Mayra V. Tarantino